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ATTORNEY'S DOCKET NO: C1037.70017US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Serial No.:

Bratzler et al. 09/800,266

Confirmation No.:

3753

Filed:

March 5, 2001

For:

IMMUNOSTIMULATORY NUCLEIC ACIDS AND CANCER

MEDICAMENT COMBINATION THERAPY FOR THE TREATMENT

OF CANCER

Examiner:

Angell, Jon E.

Art Unit:

1635

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 29th day of August, 2003.

anice A. Vatland, Reg. No. 52,318

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

[X] Information Disclosure Statement

[X] PTO Form 1449 with cited references and related applications

[X] Certificate of Mailing

[X] Check for \$180.00

[X] Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 720-3500, Boston, Massachusetts.

A check in the amount of \$180 is enclosed to cover the filing fee. If the fee is insufficient, the balance may be charged to Deposit Account 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted, Bratzler et al., Applicant(s)

By:

Janice A Vatland, Ph.D., Reg. No. 52,318

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600 Atlantic Avenue Boston, MA 02210

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Docket No. C1037.70017US00

Dated: August 29, 2003

XNDD

ATTORNEY'S DOCKET NO: C1037.70017US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):

Bratzler et al.

Serial No.:

09/800,266

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Janice A Vatland, Reg. No. 52,318

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

SUPPLEMENTAL STATEMENT FILED PURSUANT TO THE DUTY OF DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed after the mailing date of a first Office Action on the merits in the above-identified case.

The \$180 fee is enclosed.

09/04/2003 NROCHA1 00000002 09800266

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PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The Applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

Docket Number	Serial Number	Filing Date	Inventor(s)
C01037.70013.US	09/776,479	2/2/01	Bratzler et al.
C01037.70016.US	09/009,634	1/20/98	Hutcherson et al.
C01037.70018.US	09/801,839	3/8/01	Bratzler et al.
C01037.70019.US	09/920,313	8/1/01	Bratzler et al.
C01037.70021.US	09/949,194	9/7/01	Peterson et al.
C01037.70025.US	10/017,995	12/14/01	Bratzler
C01037.70041.US	TBD	7/3/03	Krieg
C01037.70042.US	TBD	7/3/03	Krieg
C01037.70043.US	TBD	7/3/03	Krieg
C01037.70044.US	TBD	7/3/03	Krieg
C01037.70045.US	TBD	7/3/03	Krieg
C01037.70046.US	TBD	6/5/03	Krieg
C01039.70020.US	09/337,584	6/21/99	Krieg et al.
C01039.70021.US	09/337,619	6/21/99	Krieg et al.
C01039.70022.US	09/337,893	6/21/99	Krieg
C01039.70023.US	09/337,636	6/21/99	Krieg
C01039.70028.US	09/361,575	7/27/99	Krieg
C01039.70029.US	09/415,142	10/9/99	Krieg et al.
C01039.70035.US	09/669,187	09/25/00	Krieg et al.
C01039.70036.US	09/559,140	4/27/00	Noll et al.
C01039.70041.US	09/655,319	9/5/00	Krieg et al.
C01039.70042.US	09/630,319	7/31/00	Krieg et al.
C01039.70043.US	09/629,477	7/31/00	Krieg et al.
C01039.70044.US	09/672,126	9/27/00	Hartmann et al.
C01039.70048.US	09/818,918	3/27/01	Krieg et al.

Docket Number	Serial Number	Filing Date	Inventor(s)
C01039.70049.US	09/824,468	04/02/01	Krieg et al.
C01039.70052.US	09/888,326	6/22/01	Weiner et al.
C01039.70053.US	09/931,583	8/16/01	Krieg et al.
C01039.70057.US	09/965,101	9/26/01	Davis et al.
C01039.70058.US	10/023,909	12/18/01	Davis et al.
C01039.70060.US	10/112,653	3/29/02	Krieg et al.
C01039.70061.US	10/161,229	6/3/02	Krieg et al.
C01039.70062.US	10/187,489	7/2/02	Krieg et al.
C01039.70063.US	10/224,523	8/19/02	Krieg et al.
C01039.70065.US	10/272,502	10/15/02	Krieg et al.
C01039.70067.US	10/300,247	11/20/02	Davis et al.
C01039.70068.US	10/306,522	11/27/02	Krieg et al.
C01039.70069.US	10/314,578	12/9/02	Krieg et al.
C01039.70070.US	10/382,822	3/6/03	Krieg et al.
C01039.70071.US	10/435,656	5/9/03	Krieg et al
C01039.70072.US	10/434,696	5/9/03	Davis et al.
C01039.70075.US	TBD	7/3/03	Krieg et al
C01039.70077.US	TBD	7/14/03	Krieg
C01039.70078.US	TBD	7/25/03	Krieg et al.
C01039.70079.US	TBD	7/25/03	Krieg et al.
C01039.70080.US	TBD	7/30/03	Krieg et al.
C01040.70006.US	09/316,199	5/21/99	McCluskie et al.
C01040.70010.US	09/768,012	1/22/01	Davis et al.
C01041.70002.US	09/241,653	2/2/99	Wagner et al.
C01041.70005.US	09/355,254	7/23/99	Wagner et al.
C01041.70010.US	09/786,436	9/3/99	Wagner et al.
C01041.70014.US	09/895,007	6/28/01	Schetter et al.
C01041.70016.US	09/954,987	9/17/01	Bauer et al.
C01041.70019.US	10/140,013	5/6/02	Schetter et al.
C01041.70029.US	10/212,133	8/1/02	Lipford et al.
C01041.70031.US	10/265,072	10/5/02	Lipford
C01041.70035.US	10/373,381	2/24/03	Wagner et al.
C01041.70037.US	10/407,952	4/4/03	Lipford et al.

The following are remarks concerning the other information cited:

PART III: Remarks

Documents cited on the attached form PTO-1449 (modified) are enclosed unless otherwise indicated on the attached form PTO-1449 (modified). It is respectfully requested that:

- 1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
- 2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
- 3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted, Bratzler et al., Applicant(s)

Janice A Vatland, Ph.D., Reg. No. 52,318 Wolf, Greenfield & Sacks, P.C.

600 Atlantic Avenue Boston, MA 02210

Telephone (617) 720-3500

Docket No. C1037.70017US00

Dated: August 29, 2003

XNDD

FORM PTO-1449/A and B (Modified)

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

ATTY. DOCKET NO.: C1037 20017 FILING DATE: March 5, 2001 Confirmation No.: 3753

APPLICANT: Bratzler et al.

GROUP ART UNIT: 1635 EXAMINER: Angell, Join

8 1 of Sheet

U.S. PATENT DOCUMENTS

APPLICATION NO.: 09/800,266

Examiner's Cite	Cite	U.S. Patent Document		Name of Patentee or Applicant of Cited	Date of Publication or of issue	
Initials# No.		Number	Kind Code	Document	of Cited Document MM-DD-YYYY	
. <u> </u>	A1	3,906,092		Hilleman et al.	09-16-1975	
	A2	5,248,670		Draper et al.	09-28-1993	
	A3	5,417,972		Bhat et al.	05-23-1995	
•	A4	5,445,938		Hanai et al.	08-29-1995	
	A5	5,491,088		Hellstrom et al.	02-13-1996	
	A6	5,663,153		Hutcherson et al.	09-02-1997	
	A7	5,679,647		Carson et al.	10-21-1997	
	A8	5,723,335		Hutcherson et al.	03-03-1998	
-	A9	5,756,097		Landucci et al.	05-26-1998	
	A10	5,786,189		Locht et al.	07-28-1998	
	A11	5,837,243		Deo et al.	11-17-1998	
	A12	5,849,719		Carson et al.	12-15-1998	
	A13	5,997,858		Tovey, et al.	12-07-1999	
	A14	6,013,639		Peyman, et al.	01-11-2000	
	A15	6,194,388		Krieg et al.	02-27-2001	
	A16	6,207,646		Krieg et al.	03-27-2001	
	A17	6,214,806		Krieg et al.	04-10-2001	
	A18	6,218,371		Krieg et al.	04-17-2001	
	A19	6,239,116		Krieg et al.	05-29-2001	
	A20	6,339,068		Krieg et al.	01-15-2002	
-	A21	6,406,705		Davis et al.	06-18-2002	
	A22	6,429,199		Krieg et al.	08-06-2002	

FOREIGN PATENT DOCUMENTS

Examiner's	Cite	Foreign Patent Document		ıment	Name of Patentee or Applicant of Cited	Date of Publication of	Translation
Initials#	No.	Office/ Country	Number	Kind Code	Document (not necessary)	Cited Document MM-DD-YYYY	(Y/N)
	Bl	EP	0 302 758	B1_	New England Medical Center Hospitals	02/08/1989	
	B2	EP	0 468 520	A2	Mitsui Toatsu Chemicals, Inc.	01/29/1992	
	В3	wo	91/12811	Al	ISIS Pharmaceuticals, Inc.	09/05/1991	
	B4	wo	92/03456	Al	ISIS Pharmaceuticals, Inc.	03/05/1992	
	B5	wo	92/18522	Al	The Salk Institute for Biological Studies	10/29/1992	
	В6	wo	92/21353	A1	Genta Incorporated	12/10/1992	
	В7	WO	94/19945	Al	ISIS Pharmaceuticals, Inc.	09/15/1994	
	В8	wo	95/05853	Al	The Regents of the University of CA	03/02/1995	

FORM PTO-1449/A and B (Modified)	APPLICATION NO.: 09/800,266	ATTY. DOCKET NO.: C1037.70017US00
INFORMATION DISCLOSURE	FILING DATE: March 5, 2001	Confirmation No.: 3753
STATEMENT BY APPLICANT	APPLICANT: Bratzler et al.	
Sheet 2 of 8	GROUP ART UNIT: 1635	EXAMINER: Angell, Jon E.

	В9	WO	95/26204	A1	ISIS Pharmaceuticals, Inc.	10/05/1995
	B10	WO	96/02555	A1	University of Iowa Research Foundation	02/01/1996
PE	B11	WO	96/02560	A1	University of NC at Chapel Hill	02/01/1996
PE JORGE	B12	WO	96/24380	A1	ICN Pharmaceuticals, Inc.	08/15/1996
1200	B13	WO	96/35782	A1	Applied Research Systems	11/14/1996
y , v	B14	wo	96/39154	A1	ISIS Pharmaceuticals, Inc	12/12/1996
97	B15	WO	97/28259	A1	The Regents of the University of CA	08/07/1997
TRADENTO	B16	wo	98/16247	Al	The Regents of the University of CA	04/23/1998
	B17	wo	98/18810	A1	University of Iowa Research Foundation	05/07/1998
	B18	WO	98/29430	Al	ICN Pharmaceuticals, Inc.	07/09/1998
	B19	wo	98/32462	Al	Wagner et al.	07/30/1998
	B20	wo	98/37919	A1	University of Iowa Research Foundation	09/03/1998
	B21	wo	98/40100	A1	Ottawa Civic Loeb Research Institute	09/17/1998
	B22	wo	98/55495	A2	Dynavax Technologies Corp.	12/10/1998
	B23	wo	98/55609	A1	The Regents of the University of CA	12/10/1998
	B24	WO	99/52549	Al	Smithkline Beecham Biologicals	10-21-1999
	B25	WO	00/14217	A2	CpG ImmunoPharmaceuticals GmbH	03/16/2000
	B26	wo	00/20039	Al	The Regents of the University of CA	04-13-2000
	B27	WO	00/62787	Al	The Regents of the University of CA	10-26-2000
	B28	WO	01/02007	Al	The Regents of the University of CA	01/11/2001
	B29	wo	01/12223	A2	Dynavax Technologies Corp.	02/22/2001

OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Cite Initials# No		Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.			
	C6	AZUMA, et al., Kekkaku, 67(9):625-635, (45-55) 1992			
	C7	BRANDA, et al., J. Lab Clin Med 128(3):329-38, 1996			
	C8	BRUNNER, et al., J Immunol. 165:6278-6286, 2000			
	C9	BURGESS, et al., Proc. Natl. Acad. Sci USA 92(9):4051-5, 1995			
	C10	CHACE, et al., Clinical Immunology and Immunopathology, (1993), 68(3):327-332			
	C11	CHU, et al., J Exp Med 186(10):1623-31, 1997			
	C12	CONSTANT, et al., Annu. Rev. Immunol., 15:297-322, 1997			
	C13	COWDERY, et al., <i>J Immunol</i> 156(12):4570-5, 1996			
	C14	DAPIC, et al. Proc. AACR, pp. 42 March 2001			
	C15	DAVIS, et al., Curr. Opin. Biotechnol. 8(5):635-40, 1997			
	C16	DAVIS, et al., J. Immunol., 160(2):870-6, 1998			
	C17	DEMATOS, et al., J. Surg. Oncol., 68(2):79-91 (1998)			
	C18	ELKINS, et al. J. Immunol. 162:2291-2298, 1999			
	C19	EUROTECH COMMISSION: EUROTECH CAPITAL REPORT Prepared by Delevoye, et al., January 2000			

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Sheet 3 of 8	GROUP ART UNIT: 1635	EXAMINER: Angell, Jon E.

TPE	C20	FUJIEDA, et al., Anticancer Res., 12:1941-1946, 1992	
-	C21	GILBOA, et al., Cancer Immunol. Immunother., 46:82-87, 1998	
- ଜ ବେହିଛି	uC22	GRANGE, et al. Lancet 345(8961):1350-2, 1995 Abstract Only	
0 2 7000	11:		
	C23	HALPERN MD et al., Cell Immunol 167(1):72-8, 1996	
Q ¹	C24	HARTMANN & KRIEG, et al. Gene Therapy, 6:893-903, 1999	
MADELLA	C25	HARTMANN & KRIEG, et al. J. Immunol. 164:944-952, 2000	
	C26	HARTMANN, et al. J. Immunol. 164:1617-1624, 2000	
	C27	HARTMANN, et al., <i>Proc. Natl. Acad. Sci.</i> USA, 96:9305-9310, 1999	
	C28	HORNER, et al., Springer Semin Immunophathol, 22(1-2):133-146, 2000	
	C29	HUANG, et al., Infection and Immunity, 67(12):6257-6263 (1999)	
	C30	HUGHES, et al. Antisense Res Dev 4:211-15, 1994	
	C31	IHO, et al. J. Immunol. 163:3642-3652, 1999	
	C32	JAKOB, et al., Int. Arch Allergy Immunol., 118(2-4):457-61, 1999	
	C33	JAKOB, et al., J. Immunol., 161(6):3042-9, 1998	
	C34	KATAOKA, et al., <i>Jpn. J. Cancer Res.</i> , 83:244-247 (1992)	
	C35	KATAOKA, et al., Jpn. J.Med. Sci. Bio., 43:171-182 (1990)	
	C36	KIMURA Y et al., J. Biochem., 116(5):991-994, 1994	
	C37		
<u> </u>		KLINMAN, et al., <i>J. Immunol.</i> 158(8):3635-9, 1997	
	C38	KLINMAN, et al., <i>Proc Natl Acad Sci USA</i> 93(7):2879-83, 1996	
	C39	KLINMAN, et al., Immunity, 11:123-129, 1999	
	C40	KRANZER, et al. <i>Immunology</i> . 99:170-178, 2000	
	C41	KRIEG, A.M. et al., "CpG motifs in bacterial DNA trigger direct B-cell activation", <i>Nature</i> 1995	
	C42	Apr 6;374(6522):546-9	
	C42	KRIEG, A.M. et al., "Modification of antisense phosphodiester oligodeoxynucleotides by a 5' cholesteryl moiety increases cellular association and improves efficacy", <i>Proc Natl Acad Sci U S A</i> .	
		1993 Feb 1;90(3):1048-52	
	C43	KRIEG, A.M. et al., "Oligodeoxynucleotide Modifications Determine the Magnitude of B Cell	
		Stimulation by CpG Motifs", Antisense & Nucleic Acid Drug Development, 1996, Pages 133-139,	
		Vol. 6.	
	C44	KRIEG, A.M. et al., "Phosphorothioate Oligodeoxynucleotides: Antisense or Anti-Protein?",	
	C45	Antisense Research and Development, 1995, Page 241, Vol. 5, Mary Ann Liebert, Inc.	
	C45	KRIEG, A.M. et al., "Uptake of Oligodeoxyribonucleotides by Lymphoid Cells is Heterogenous and Inducible", Antisense Research and Development, 1991, Pages 161-171, Vol. 1, Mary Ann	
		Liebert, Inc.	
	C46	KRIEG, A.M., "An innate immune defense mechanism based on the recognition of CpG motifs in	
		microbial DNA", J. Lab. Clin. Med., 1996, Pages 128-133, Vol. 128	
	C47	KRIEG, A.M., "Chapter 24: Leukocyte Stimulation by Oligodeoxynucleotides", Applied	
	<u> </u>	Antisense Oligonucleotide Technology, 1998, Pages 431-448, Wiley-Liss, Inc.	
	C48	KRIEG, A.M., "CpG DNA: A Pathogenic Factor in Systemic Lupus Erythematosus?", Journal of	
	1	Clinical Immunology, 1995, Pages 284-292, Vol. 15, No. 6	
	C49	KRIEG, et al. Pharmacol Ther. 84:113-120, 1999	
	C50	KURAMOTO, E. et al., "Changes of Host Cell Infiltration into Meth A Fibrosarcoma Tumor	
	-	During the Course of Regression Induced by Injections of a BCG Nucleic Acid Fraction", Int. J.	
	<u></u>	Immunopharmac., 1992, Pages 773-782, Vol. 14, No. 5.	

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INFORMATION DISCLOSURE	FILING DATE: March 5, 2001	Confirmation No.: 3753
STATEMENT BY APPLICANT	APPLICANT: Bratzler et al.	
Sheet 4 of 8	GROUP ART UNIT: 1635	EXAMINER: Angell, Jon E.

	C51	KURAMOTO, E. et al., "In Situ Infiltration of Natural Killer-Like Cells Induced by Intradermal	
	00.	Injection of the Nucleic Acid Fraction from BCG", <i>Microbiol. Immunol.</i> , 1989, Pages 929-940, Vol. 33, No. 11	
TPEVE	C52	KURAMOTO, E. et al., "Oligonucleotide Sequences Required for Natural Killer Cell Activation", Jpn. J. Cancer Res., November 1992, Pages 1128-1131, Vol. 83	
7 02 TM	C53	LACOUR, J., "Clinical Trials Using Polyadenylic-Polyuridylic Acid as an Adjuvant to Surgery in Treating Different Human Tumors", Journal of Biological Response Modifiers, 1985, Pages 538-543, Vol. 4.	
PADE LACK	C54	LANG, R. et al., "Guanosine-rich oligodeoxynucleotides induce proliferation of macrophage progenitors in cultures of murine bone marrow cells", <i>Eur. J. Immunol.</i> , 1999, Pages 3496-3506, Vol. 29.	
	C55	LEDERMAN, S. et al., "Polydeoxyguanine Motifs in a 12-mer Phosphorothioate Oligodeoxynucleotide Augment Binding to the v3 Loop of HIV-1 gp120 and Potency of HIV-1 Inhibition Independently of G-Tetrad Formation", Antisense & Neucleic Acid Drug Development, 1996, Pages 281-289, Vol. 6.	
	C56	LEE, P.P. et al., "An Oligonucleotide Blocks Interferon-γ Signal Transduction", <i>Transplantation</i> , November 15, 1996, Pages 1297-1301, Vol. 62, No. 9.	
	C57	LIPFORD, et al., Eur. J. Immunol., 27:3420-6, 1997	
	C58	LIPFORD, et al., <i>Trends Microbiol.</i> , 6(12):496-500 (1998)	
	C59	LIPFORD, G.B. et al., "CpG-containing synthetic oligonucleotides promote B and cytotoxic T cell responses to protein antigen: a new class of vaccine adjuvants", <i>Eur. J. Immunol.</i> , 1997, Pages 2340-2344, Vol. 27.	
	C60	LIU, H.M. et al., "Immunostimulatory CpG Oligodeoxynucleotides Enhance the Immune Response to Vaccine Strategies Involving Granulocyte-Macrophage Colony-Stimulating Factor", <i>Blood</i> , November 15, 1998, Pages 3730-3736, Vol. 92, No. 10.	
	C61	LOKE, S.L. et al., "Delivery of <i>c-myc</i> Antisense Phosphorothioate Oligodeoxynucleotides to Hematopoietic Cells in Culture by Liposome Fusion: Specific Reduction in <i>c-myc</i> Protein Expression Correlates with Inhibition of Cell Growth and DNA Synthesis", <i>Current Topics in Microbiology and Immunology</i> , 1988, Pages 282-289, Vol. 141.	
	C62	MACAYA, R.F. et al., "Thrombin-binding DNA aptamer forms a unimolecular quadruplex structure in solution", <i>Proc. Natl. Acad. Sci. USA</i> , April 1993, 90:3745-3749.	
	C63	MACFARLANE, D.E. et al., "Antagonism of Immunostimulatory CpG-Oligodeoxynucleotides by Quinacrine, Chloroquine, and Structurally Related Compounds", <i>The Journal of Immunology</i> , 1998, Pages 1122-1131, Vol. 160, No. 3.	
	C64	MALTESE, J.Y. et al., "Sequence context of antisense RelA/NF-κB phosphorothioates determines specificity", <i>Nucleic Acids Research</i> , 1995, Pages 1146-1151, Vol. 23, No. 7.	
	C65	MASHIBA, et al. Jpn. J. Med. Sci. Biol., 41:197-202, 1988	
	C66	MASTRANGELO, M.J. et al., "Gene Therapy for Human Cancer: An Essay for Clinicians", Seminars in Oncology, February 1996, Pages 4-21, Vol. 23 No. 1	
	C67	MATSON, S. et al., "Nonspecific Suppression of [3H]Thymidine Incorporation by "Control" Oligonucleotides", Antisense Research and Development, 1992, Pages 325-330, Vol. 2.	
	C68	MCCLUSKIE, M.J. et al., "Oral, intrarectal and intranasal immunizations using CpG and non-CpG oligodeoxynucleotides as adjuvants", <i>Vaccine</i> , 2001, Pages 413-422, Vol. 19.	
	C69	MCINTYRE, K.W. et al., "A Sense Phosphorothioate Oligonucleotide Directed to the Initiation Codon of Transcription Factor NF-kB p65 Causes Sequence-Specific Immune Stimulation", Antisense Research and Development, 1993, Pages 309-322, Vol. 3.	
	C70	MESSINA, J.P. et al., "Stimulation of <i>In Vitro</i> Murine Lymphocyte Proliferation by Bacterial DNA", <i>The Journal of Immunology</i> , September 15, 1991, Pages 1759-1764, Vol. 147, No. 6.	

FORM PTO-1449/A and B (Modified)	APPLICATION NO.: 09/800,266	ATTY. DOCKET NO.: C1037.70017US00
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STATEMENT BY APPLICANT	APPLICANT: Bratzler et al.	
Sheet 5 of 8	GROUP ART UNIT: 1635	EXAMINER: Angell, Jon E.

E	C71	MESSINA, J.P. et al., "The Influence of DNA Structure on the <i>in Vitro</i> Stimulation of Murine Lymphocytes by Natural and Synthetic Polynucleotide Antigens", <i>Cellular Immunology</i> , 1993, Pages 148-157, Vol. 147.	
0 3 2 2 2 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3	C72	MICHELSON, A.M. et al., "Polyadenylic-Polyuridylic Acid in the Cotreatment of Cancer (42055)", Proceedings of the Society for Experimental Biology and Medicine, 1985, Pages 1-8, Vol. 179.	
TRADELAR	C73	MOJCIK, C.F. et al., "Administration of a Phosphorothioate Oligonucleotide Antisense to Murine Endogenous Retroviral MCF env Causes Immune Effects in Vivo in a Sequence-Specific Manner", Clinical Immunology and Immunopathology, May 1993, Pages 130-136, Vol. 67, No. 2.	
	C74	MORAHAN, P.S. et al., "Comparative Analysis of Modulators of Nonspecific Resistance Against Microbial Infections", Immunopharmacology of Infectious Diseases: Vaccine Adjuvants and Modulators of Non-Specific Resistance, 1987, Pages 313-324.	
	C75	NEW ENGLAND BIOLABS 1988-1989 Catalog; #1230, #1602 and #1202	
	C76	PARKER, et al. Cancer Gene Therapy. 3:175-185, 1996	
	C77	PETERSON, et al., Bio. Pharm., 47(1):127-128, 1994	
	C78	ROSENBERG, S.A. et al., "Immunologic and therapeutic evaluation of a synthetic peptide vaccine for the treatment of patients with metastatic melanoma", <i>Nature Medicine</i> , March 1998, Pages 321-327, Vol. 4, No. 3	
	C79	SR PHARMA PLC, "Vaccine adjuvants in medicine and the role of SRL 172" from SR Pharma website at http://www.srpharma.com/immune.html accessed December 10, 1999. 4 pages.	
	C80	SR PHARMA PLC., "NIH funded study demonstrates benefits with use of SRL172 as a adjunct to combination chemotherapy in TB." from SR Pharma website at http://www.srpharma.com/jun15.html . Dated June 15, 1998, accessed on December 10, 1999, 1 page.	
	C81	SR PHARMA PLC, "SR Pharma Company Profile" from SR Pharma website at	
	C82	http://www.srpharma.com/comp_prof.html accessed December 10, 1999, 3 pages.	
	C82	SARMIENTO, U.M. et al., "In Vivo Toxicological Effects of rel A Antisense Phosphorothioates in CD-1 Mice", Antisense Research and Development, 1994, Pages 99-107, Vol. 4.	
	C83	SATO, Y. et al., "Immunostimulatory DNA Sequences Necessary for Effective Intradermal Gene Immunization", Science, July 19, 1996, Pages 352-354, Vol. 273	
	C84	SCHNELL, N. et al., "Identification and characterization of a Saccharomyces cerevisiae gene (PAR1) conferring resistance to iron chelators", Eur. J. Biochem., 1991, Pages 487-493, Vol. 200, FEBS	
	C85	SCHWARTZ, D.A. et al., "CpG Motifs in Bacterial DNA Cause Inflammation in the Lower Respiratory Tract", <i>The Journal of Clinical Investigation</i> , July 1997, Pages 68-73, Vol. 100, No. 1	
	C86	SCHWARTZ, D.A. et al., "Endotoxin responsiveness and grain dust-induced inflammation in the lower respiratory tract", Am. J. Physiol., 1994, Pages L609-L617, Vol. 267(5 Pt 1).	
	C87	SCHWARTZ, D.A. et al., "The Role of Endotoxin in Grain Dust-Induced Lung Disease", Am. J. Respir. Crit. Care Med., 1995, Pages 603-608, Vol. 152	
	C88	SEGAL, B.M. et al., "Microbial Products Induce Autoimmune Disease by an IL-12-Dependent Pathway", J. Immunol., 1997, Pages 5087-5090, Vol. 158.	
	C89	SHIMADA, S. et al., "Antitumor Activity of the DNA Fraction from Mycobacterium bovis BCG. II. Effects on Various Syngeneic Mouse Tumors", JNCI, March 1985, Pages 681-688, Vol. 74, No. 3	
	C90	SHIMADA, S. et al., "In Vivo Augmentation of Natural Killer Cell Activity with a Deoxyribonucleic Acid Fraction of BCG", Jpn. J. Cancer Res. (Gann), August 1986, Pages 808-816, Vol. 77	
	C91	SHIRAKAWA, T. et al., "The Inverse Association Between Tuberculin Responses and Atopic	-+

FORM PTO-1449/A and B (Modified)	APPLICATION NO.: 09/800,266	ATTY. DOCKET NO.: C1037,70017US00
INFORMATION DISCLOSURE	FILING DATE: March 5, 2001	Confirmation No.: 3753
STATEMENT BY APPLICANT	APPLICANT: Bratzler et al.	
Sheet 6 of 8	GROUP ART UNIT: 1635	EXAMINER: Angell, Jon E.

		Disorder", Science, January 3, 1997, Pages 77-79, Vol. 275	
	C92	SPARWASSER, T. et al., "Bacterial DNA and immunostimulatory CpG oligonucleotides trigger	
		maturation and activation of murine dendritic cells", Eur. J. Immunol., 1998, Pages 2045-2054, Vol. 28.	
	C93	SPARWASSER, T. et al., "Macrophages sense pathogens via DNA motifs: induction of tumor	
E		necrosis factor-α-mediated shock", Eur. J. Immunol., 1997, Pages 1671-1679, Vol. 27.	
	C94	SPIEGELBERG, H.L. et al., "Recognition of T Cell Epitopes and Lymphokine Secretion by Rye Grass Allergen <i>Lolium perenne</i> 1-Specific Human T Cell Clones", <i>J. Immunol.</i> , May 1, 1994, Pages 4706-4711, Vol. 152, No. 9.	
6 L	C95	STEIN, C.A. et al., "Oligodeoxynucleotides as Inhibitors of Gene Expression: A Review", Cancer Research, May 15, 1988, Pages 2659-2668, Vol. 48	
	C96	STEVENSON, H.C. et al., "The Treatment of Cancer with Activated Cytotoxic Leukocyte	
& TRACES		Subsets", Artif. Organs, 1988, Pages 128-136, Vol. 12, No. 2, International Society for Artificial Organs.	
	C97	SUBRAMANIAN, P.S. et al., "Theoretical considerations on the "spine of hydration" in the	
		minor groove of d(CGCGAATTCGCG)· d(GCGCTTAAGCGC): Monte Carlo computer	
		simulation", Proc. Natl. Acad. Sci. USA, March 1988, Pages 1836-1840, Vol. 85	
	C98	SUN, S. et al., "Mitogenicity of DNA from Different Organisms for Murine B Cells", J.	
		Immunol., 1997, Pages 3119-3125, Vol. 159.	
	C99	SUN, S. et al., "Multiple effects of immunostimulatory DNA on T cells and the role of type I	
		interferons", Springer Semin Immunophathol., 2000, Pages 77-84, Vol. 22.	
	C100	TALMADGE, J.E. et al., "Immunomodulatory Effects in Mice of Polyinosinic-Polycytidylic Acid	
	0.00	Complexed with Poly-L-lysine and Carboxymethylocellulose", Cancer Research, March 1985,	
		Pages 1058-1065, Vol. 45	
	C101	TANAKA, T. et al., "An Antisense Oligonucleotide Complementary to a Sequence in Iy2b	
	0101		
		Increases γ2b Germline Transcripts, Stimulates B Cell DNA Synthesis, and Inhibits	
		Immunoglobulin Secretion", The Journal of Experimental Medicine, February 1992, Pages 597-	
	C102	607, Vol. 175	
	C102	TANG, D. et al., "Genetic immunization is a simple method for eliciting an immune response", <i>Nature</i> , March 12, 1992, Pages 152-154, Vol. 356	
	C103	THORNE, P.S., "Experimental Grain Dust Atmospheres Generated by Wet and Dry	
		Aerosolization Techniques", American Journal of Industrial Medicine, 1994, Pages 109-112, Vol. 25	
	C104	THREADGILL, D.S. et al., "Mitogenic synthetic polynucleotides suppress the antibody response to a bacterial polysaccharide", Vaccine, 1998, Pages 76-82, Vol. 16, No. 1	
	C105	TJOA, B.A. et al., "Evaluation of Phase I/II Clinical Trials in Prostate Cancer with Dendritic Cells and PSMA Peptides", <i>The Prostate</i> , 1998, Pages 39-44, Vol. 36	
	C106	TOKUNAGA, T. et al, "A Synthetic Single-Stranded DNA, Poly(dG.dC), Induces Interferon-α/β	-
		and -γ, Augments Natural Killer Activity, and Suppresses Tumor Growth", Jpn. J. Cancer Res. (Gann), June 1988, Pages 682-686, Vol. 79	
	C107	TOKUNAGA, T. et al., "Antitumor Activity of Deoxyribonucleic Acid Fraction from	
		Mycobacterium bovis BCG. I. Isolation, Physicochemical Characterization, and Antitumor	
		Activity", JNCI, April 1984, Pages 955-962, Vol. 72, No. 4	
_	C108	TOKUNAGA, T. et al., "Synthetic Oligonucleotides with Particular Base Sequences from the	
		cDNA Encoding Proteins of Mycobacterium bovis BCG Induce Interferons and Activate Natural	
		Killer Cells", 1992, Microbiol. Immunol., 1992, Pages 55-66, Vol. 36, No. 1	
	C109	TOPALIAN, S.L. et al., "Expansion of human tumor infiltrating lymphocytes for use in	
		immunotherapy trials", Journal of Immunological Methods, 1987, Pages 127-141, Vol. 102	

FORM PTO-1449/A and B (Modified)	APPLICATION NO.: 09/800,266	ATTY. DOCKET NO.: C1037.70017US00
INFORMATION DISCLOSURE	FILING DATE: March 5, 2001	Confirmation No.: 3753
STATEMENT BY APPLICANT	APPLICANT: Bratzler et al.	
	GROUP ART UNIT: 1635	EXAMINER: Angell, Jon E.

	C110	TORPEY III, D. et al., "Effects of Adoptive Immunotherapy with Autologous CD8 ⁺ T	
		Lymphocytes on Immunologic Parameters: Lymphocyte Subsets and Cytotoxic Activity", Clinical	
		Immunology and Immunopathology, September 1993, Pages 263-272, Vol. 68, No. 3	
	C111	UHLMANN, E. et al., "Antisense Oligonucleotides: A New Therapeutic Principle", Chemical Reviews, June 1990, Pages 544-584, Vol. 90, No. 4	
EVENO	C112		
~ 5.00g	C113	VIL'NER, et al. Antibiotiki 29(6):450-3, 1984. ABSTRACT ONLY	
9 2 FR FB	C114		
,	C115		-+
BADEONO	C116	VIL'NER, et al. Vopr. Virusol. 33(3):331-35, 1988. ABSTRACT ONLY	
DRAD	C117	VIL'NER, et al. Vopr. Virusol., 30(3):337-340, 1985. ABSTRACT ONLY	
	C118		
	C119		
	C120	WALLACE, R.B. et al., "Oligonucleotide Probes for the Screening of Recombinant DNA Libraries", <i>Methods in Enzymology</i> , 1987, Pages 432-442, Vol. 152.	
	C121	WARREN, T.L. et al., "APC Stimulated by CpG Oligodeoxynucleotide Enhance Activation of MHC Class I-Restricted T Cells", J. Immunol., 2000, Pages 6244-6251, Vol. 165	
	C122	WEISS, R., "Upping the Antisense Ante – Scien tists bet on profits from reverse genetics",	
		Science News, February 16, 1991, Pages 108-109, Vol. 139	
	C123	WHALEN, R.G., "DNA Vaccines for Emerging Infectious Diseases: What If?", Emerging	
		Infectious Diseases, July-September 1996, Pages 168-175, Vol. 2, No. 3	
	C124	WLOCH, M.K. et al., "The Influence of DNA Sequence on the Immunostimulatory Properties of	
	C125	Plasmid DNA Vectors", <i>Human Gene Therapy</i> , July 1, 1998, Pages 1439-1447, Vol. 9. WOOLDRIDGE, J.E. et al., "Immunostimulatory Oligodeoxynucleotides Containing CpG Motifs	-+
	0.25	Enhance the Efficacy of Monoclonal Antibody Therapy of Lymphoma", <i>Blood</i> , April 15, 1997, Pages 2994-2998, Vol. 89, No. 8	
····	C126	WOOLDRIDGE, J.E. et al., "Select unmethylated CpG oligodeoxynucleotide improve antibody-	
		dependent cellular cytotoxicity in vitro and in vivo", Proceedings of the American Association for Cancer Research No. 3253, March 1996, Page 477, Vol. 37	
	C127	WU-PONG, S., "Oligonucleotides: Opportunities for Drug Therapy and Research", Pharmaceutical Technology, October 1994, Pages 102-114, Vol. 18	
	C128	YAMAMOTO, S. et al., "DNA from Bacteria, but Not from Vertebrates, Induces Interferons, Activates Natural Killer Cells and Inhibits Tumor Growth", <i>Microbiol. Immunol.</i> , 1992, Pages 983-997, Vol. 36, No. 9	
	C129	YAMAMOTO, S. et al., "In vitro Augmentation of Natural Killer Cell Activity and Production of Interferon-α/β and -γ with Deoxyribonucleic Acid Fraction from Mycobacterium bovis BCG", Jpn. J. Cancer Res. (Gann), July 1988, Pages 866-873, Vol. 79	
	C130	YAMAMOTO, S. et al., "Unique Palindromic Sequences in Synthetic Oligonucleotides are Required to Induce INF and Augment INF-Mediated Natural Killer Activity", <i>The Journal of Immunology</i> , June 15, 1992, Pages 4072-4076, Vol. 148, No. 12	
· ·	C131	YAMAMOTO, S., "Mode of Action of Oligonucleotide Fraction Extracted from Mycobaterium bovis BCG", Kekkaku, 1994, Pages 29-32, Vol. 69, No. 9	
	C132	YAMAMOTO, T. et al., "Ability of Oligonucleotides with Certain Palindromes to Induce Interferon Production and Augment Natural Killer Cell Activity is Associated with Their Base	

FORM PTO-1449/A and B (Modified)	APPLICATION NO.: 09/800,266	ATTY. DOCKET NO.: C1037.70017US00
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STATEMENT BY APPLICANT	APPLICANT: Bratzler et al.	
Sheet 8 of 8	GROUP ART UNIT: 1635	EXAMINER: Angell, Jon E.

		Length", Antisense Research and Development, 1994, Pages 119-122, Vol. 4	
	C133	YAMAMOTO, T. et al., "Lipofection of Synthetic Oligodeoxyribonucleotide Having a	
DIBE/		Palindromic Sequence of AACGTT to Murine Splenocytes Enhances Interferon Production and	
Sel.		Natural Killer Activity", Microbiol. Immunol., 1994, Pages 831-836, Vol. 38, No. 10	
3.110	C134	YAMAMOTO, T. et al., "Synthetic Oligonucleotides with Certain Palindromes Stimulate	
, 03 mg 3	5 ;	Interferon Production of Human Peripheral Blood Lymphocytes in vitro", Jpn. J. Cancer Res.,	
ζ.		August 1994, Pages 775-779, Vol. 85	
(V)	C135	YI, A.K. et al., "CpG Oligodeoxyribonucleotides Rescue Mature Spleen B Cells from Spontaneous	
ADENA PA CE		Apoptosis and Promote Cell Cycle Entry", The Journal of Immunology, 1998, Pages 5898-5906,	
The state of the s		Vol. 160, No. 12	
	C136	YI, A.K. et al., "Cutting Edge: Rapid Induction of Mitogen-Activated Protein Kinases by Immune	
		Stimulatory CpG DNA", The Journal of Immunology, November 1, 1998, Pages 4493-4497, Vol.	
		161, No. 9	
<u> </u>	C137	YI, A.K. et al., "IFN-y Promotes IL-6 and IgM Secretion in Response to CpG Motifs in Bacterial	
		DNA and Oligodeoxynucleotides", <i>The Journal of Immunology</i> , 1996, Pages 558-564, Vol. 156,	l
		No. 2	
	C138	YI, A.K. et al., "Rapid Immune Activation by CpG Motifs in Bacterial DNA-Systemic Induction	
		of IL-6 Transcription Through an Antioxidant-Sensitive Pathway", J Immunol, 157:5394-5402,	
		1996.	
	C139	ZHAO, Q. et al., "Comparison of Cellular Binding and Uptake of Antisense Phosphodiester,	
		Phosphorothioate, and Mixed Phosphorothioate and Methylphosphonate Oligonucleotides",	
		Antisense Research and Development, 1993, Pages 53-66, Vol. 3, Mary Ann Liebert, Inc.	
	C140	ZHAO, Q. et al., "Stage-Specific Oligonucleotide Uptake in Murine Bone Marrow B-Cell Precursors", Blood,	
		December 1, 1994, Pages 3660-3666, Vol. 84, No. 11	

EXAMINER	DATE CONSIDERED	

#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.